

Those suffering with psoriasis are also at an increased risk for numerous other serious, chronic and life-threatening conditions such as heart disease, diabetes and mental health conditions. These co-morbidities inflict a significant economic and social burden on society in addition to the individuals with psoriasis. This legislation would direct the Secretary of Health and Human Services to convene a summit of researchers, public health professionals, patient advocacy organizations, academic institutions, and Federal and State policymakers on the current research, treatment, education, and quality-of-life activities conducted or supported by the Federal Government with respect to psoriasis and psoriatic arthritis, including psoriasis and psoriatic arthritis related co-morbidities. A comprehensive report from this summit would provide a roadmap for future activities necessary to address current gaps and better our chances of finding a cure. Lastly, the bill would require a study and report by the Institute of Medicine to address health insurance and prescription drug coverage as they relate to medications and treatments for psoriasis and psoriatic arthritis. We must ensure that these patients receive the best regimen and most appropriate care for their disease.

In closing, I would like to commend the National Psoriasis Foundation for their more than four decades of leadership and work to improve quality of life for people with psoriasis and psoriatic arthritis. I would also like to extend great thanks to my constituents, John and Vivian Latella, who have shared their personal stories of the difficulties of living with psoriasis. For them, and for the millions of Americans suffering from this disease, I urge my colleagues to join me in cosponsoring the Psoriasis and Psoriatic Arthritis Research, Cure, and Care Act.

PAXIL

Mr. GRASSLEY. Madam President, for the last few years, I have been looking at how drug companies try and influence medical care in America. Companies can do this by, for example, creating studies favorable to their drugs, by hiring doctors to promote their products, and in some cases even intimidating critics of their drugs.

Today, I would like to talk about a different tactic by drug companies hiding data. I don't mean that they actually hide the data. But they make these numbers so difficult to find that they might as well be invisible.

Last February, I asked GlaxoSmithKline to turn over a couple of reports on Paxil, a drug used to treat depression. These reports were written by Dr. Joseph Glenmullen, a professor of psychiatry at Harvard.

Based on the review of documents uncovered in litigation, Dr. Glenmullen concluded that GlaxoSmithKline knew for almost two decades that Paxil is as-

sociated with an increased risk of suicide. He submitted these reports as an expert witness in several lawsuits now pending around the country.

So what did GlaxoSmithKline do with these reports? Well, the company tried to hide them. They went to the judge and asked to have Dr. Glenmullen's report and all the confirming documents placed under seal—that means that no member of the public could see them. In fact, Glaxo has been doing everything possible to ensure that this information remains under court seal.

It seems to me that GlaxoSmithKline tried to hide these reports because they seem to demonstrate what the company knew—that Paxil was associated with an increased risk of suicide based on the company's own studies. In fact, Dr. Glenmullen argues that GlaxoSmithKline knew this when they submitted the New Drug Application to the Food and Drug Administration back in 1989.

Essentially, it looks like GlaxoSmithKline bamboozled the FDA.

How did GlaxoSmithKline get away with this? Easy, they just moved around numbers in their studies to make it look like Paxil was safe. Here is how Dr. Glenmullen says they did it. GlaxoSmithKline ran several studies comparing people on Paxil against people on a placebo, in other words, a sugar pill.

If a patient attempted suicide before a study began—let me emphasize this: Before the study began—that person was automatically put into the placebo group. That means the company was comparing Paxil users against patients who were already prone to suicide. So when you compared the placebo numbers to the Paxil numbers, it looked like Paxil was the same as the placebo.

But, when Dr. Glenmullen re-analyzed the data, he found that Paxil WAS associated with a risk for suicide. And it looks like this is what GlaxoSmithKline was trying to hide from the American public.

Thankfully, a judge in Kansas made one of Dr. Glenmullen's reports public.

Finally, I would like to address GlaxoSmithKline's responses to my questions about whether it hid data on Paxil. I am unhappy to say that Glaxo's answers were a little more than word games. I don't wish to use the word "lie" but let me say this: their answers were less than candid.

Let me give you one example. In a letter to GlaxoSmithKline, I asked them when they learned that Paxil was associated with suicide risk. They wrote back that they "detected no signal of any possible association between Paxil and suicidality in adult patients until late February 2006 . . ."

So GSK claims to a U.S. Senator they knew nothing about suicidality in adults until February 2006. But in the United Kingdom, government investigators found that the company had the data back in 1998.

Two weeks after I received the letter from GSK, England's Medicines and

Healthcare products Regulatory Agency released a report on Paxil.

The report concluded that data from GlaxoSmithKline's own clinical trials confirmed that patients under 18 had a higher risk of suicidal behavior. This report involved 4 years of investigation by this agency which is England's counterpart to our FDA. It was the largest most thorough report in the history of that agency.

According to the Medicines and Healthcare products Regulatory Agency, the only reason that criminal charges were not filed in the UK is because "the legislation in force at the time was not sufficiently strong enough . . ." So the company didn't get off because it didn't do anything wrong. It got off because the laws in UK did not address such situations.

Today, I am asking the FDA to take a look at the same information that was examined in the UK. And I am asking the FDA if we need to change any laws here in the United States.

We cannot live in a nation where drug companies are less than candid, hide information and attempt to mislead the FDA and the public. These companies are selling drugs that we put in our bodies, not sneakers. When they manipulate or withhold data to hide or minimize findings about safety and/or efficacy, they put patient safety at risk. And with drugs like Paxil, the risks are too great.

The CEO of GlaxoSmithKline, Jean-Pierre Garnier, is resigning. I hope that the company's new leadership will do right by the public and be more open about side effects of their products.

What happened with Paxil, as well as, in my investigations involving the painkiller Vioxx and the antibiotic Ketek are only a few examples of why it is important that bad actors be held accountable when they withhold data, submit questionable or fraudulent data, or attempt to mislead the FDA, the medical community, and the public.

That is why I am also working on legislation that would require that companies certify to the FDA that they gave the FDA complete and accurate data related to the safety and efficacy of their products and that the information is not false or misleading. If a company knowingly violates those certifications, it could be subject to civil and possibly criminal penalties.

NEUROFIBROMATOSIS AWARENESS

Mr. COBURN. Madam President, I rise today to highlight the difficulties caused by neurofibromatosis, NF, the work currently being done by the Federal Government to address this difficult disease, and the importance of awareness about NF.

NF is a genetic disorder of the nervous system, which causes tumors to form on the nerves anywhere in the body at any time. NF is a progressive disorder and is one of the most common genetic disorders in the United